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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,853	08/27/2001	Catherine E. Burgess	21402-099 (CURA-399)	3236
	7590 09/01/2004		EXAM	INER
MILLENNIUM PHARMACEUTICALS, INC. 40 Landsdowne Street		MARTINELL, JAMES		
	AMBRIDGE, MA 02139		ART UNIT	PAPER NUMBER
			1631	
			DATE MAILED: 09/01/2004	.

Please find below and/or attached an Office communication concerning this application or proceeding.

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		'n

Office Action Summary

7) Claim(s) 53, 55-59, 66, 69, 70, and 73 is/are objected to.

9) The specification is objected to by the Examiner.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application No.	Applicant(s)		
09/939,853	BURGESS ET AL.	BURGESS ET AL.	
Examiner	Art Unit		
James Martinell	1631	·	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status	
1)⊠ 2a)□ 3)□	Responsive to communication(s) filed on <u>22 June 2004</u> . This action is FINAL . 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.
Dispositi	on of Claims
5)⊠	Claim(s) <u>5,8-14,19-21,39,42,46,47 and 50-73</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. Claim(s) <u>71</u> is/are allowed.
6)⊠	Claim(s) <u>5,8-14,19-21,39,42,46,47,50-52,54,60-65,67,68 and 72</u> is/are rejected.

Application Papers

10)	The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.
	under 35 U.S.C. § 119
12)[]	Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. _
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attach	ment(s	1
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1) 🖂	Notice of References Cited (PTO-892)
2) 🔲	Notice of Draftsperson's Patent Drawing Review (PTO-94)

8) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____

4) 🔲	Interview Summary (PTO-413))
	Paper No(s)/Mail Date.	

5) Notice of Informal Patent Application (PTO-152)

6) [Other:	
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Claims 53, 55-59, 66, 69, 70, and 73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 8-14, 19-21, 39, 42, 46, 47, 50, 51, 61-64, and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 5 recites "a mature form of SEQ ID NO: 75", implying that there is more than one mature form of SEQ ID NO: 75. However, at page 94,lines 23-24, the application states, "SignalP, Psort and/or Hydropathy results predict that NOV13 does not have a known signal peptide". Thus, the instant application does not disclose the mature forms of SEQ ID NO: 75.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

⁽b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 52, 65, and 67 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by any one of Adams et al (Nature 377 (Suppl), 3, Accession No. AA309769 (1995),), Nakayama et al (Genomics 51(1), 27, Accession No. AB011527 (1998)), or Mahairas et al (Accession No. B45150 (October 21, 1997)). Adams et al discloses a DNA sequence (*i.e.* Accession No. AA309769) that shares 57 contiguous nucleotides with SEQ ID NO: 74 (compare SEQ ID NO: 74, nucleotides 1127-1183 to the sequence of Accession No. AA309769, nucleotides 1-57). Nakayama et al discloses a DNA sequence (*i.e.* Accession

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No. AB011527) that shares 23 contiguous nucleotides with SEQ ID NO: 74 (compare SEQ ID NO: 74, nucleotides 305-327 to Accession No. AB011527, nucleotides 13026-13048). Mahairas et al discloses a DNA sequence (*i.e.* Accession No. B45150) that shares 103 contiguous nucleotides with SEQ ID NO: 74 (compare SEQ ID NO: 74, nucleotides 487-589 to Accession No. B45150, nucleotides 210-312). The DNA of each of the references is embraced by claim 52, part c). Claim 52, part c) is construed as open language even though the term "consisting of" is used in the claim because the phrasing of the claim does not make clear whether all of the nucleotides in the claimed nucleic acid share common sequence with the sequence of SEQ ID NO: 74. Since the DNAs of each of the references were sequenced, they were necessarily contained within vectors and host cells (claims 65 and 67).

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Adams et al (Nature 377 (Suppl), 3, Accession No. AA309769 (1995),), Nakayama et al (Genomics 51(1), 27, Accession No. AB011527 (1998)), or Mahairas et al (Accession No. B45150 (October 21, 1997)) in view of Wallace et al (Methods Enzymol. 152: 432 (1987)). Adams et al discloses a DNA sequence (i.e. Accession No. AA309769) that shares 57 contiguous nucleotides with SEQ ID NO: 74 (compare SEQ ID NO: 74, nucleotides 1127-1183 to the sequence of Accession No. AA309769, nucleotides 1-57). Nakayama et al discloses a DNA sequence (i.e. Accession No. AB011527) that shares 23 contiguous nucleotides with SEQ ID NO: 74 (compare SEQ ID NO: 74, nucleotides 305-327 to Accession No. AB011527, nucleotides 13026-13048). Mahairas et al discloses a DNA sequence (i.e. Accession No. B45150) that shares 103 contiguous nucleotides with SEQ ID NO: 74 (compare SEQ ID NO: 74, nucleotides 487-589 to Accession No. B45150, nucleotides 210-312). The DNA of each of the references is embraced by claim 52, part c). Claim 52, part c) is construed as open language even though the term "consisting of" is used in the claim because the phrasing of the claim does not make clear whether all of the nucleotides in the claimed nucleic acid share common sequence with the sequence of SEQ ID NO: 74. Wallace et al teaches the creation and use of oligonucleotide probes for the detection of nucleic acids by nucleic acid molecular hybridization assays (e.g., pages 434-435). It would have been obvious for one of ordinary skill in the art at the time the invention was made to create probes in the manner of Wallace et al complementary to

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the DNA of any one of the primary references in order to detect in a nucleic acid molecular hybridization assay the DNA of any one of the primary references.

Claim 71 is allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

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PLEASE NOTE THE NEW FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

James Martinell, Ph.D. Primary Examiner Art Unit 1631

8/27/04